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# EUROPEAN PATENT APPLICATION

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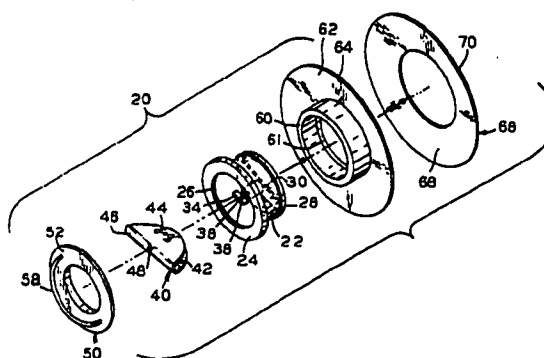
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54 Method and apparatus for a tracheal valve.

57 An externally worn tracheal valve has a valve assembly (20) supporting a flexible, resilient lightweight diaphragm (40) centrally thereof. The diaphragm (40) is folded towards the trachea so that air expelled from the trachea will tend to unfold the diaphragm to an extended position to close the valve. During normal breathing, the diaphragm (40) remains at least partially folded and the valve remains open. During voice exhalation, the diaphragm (40) extends to close the valve. During high pressure coughing exhalation, the diaphragm (40) may evert, opening the valve to release excessive pressure.



- 1 -

Method and Apparatus for a Tracheal Valve

This invention is in the field of tracheal valves used after a tracheotomy for breathing and in conjunction with a voice prosthesis device.

Numerous efforts have been made at providing a  
5 tracheal valve that will remain open to accommodate normal breathing, will close during speaking so that the voice exhalation will be diverted to the larynx or a voice prosthesis device, and will open upon coughing to relieve excessive internal pressure. Since normal  
10 breathing, voice exhalation, and cough exhalation are accompanied by progressively increasing pneumatic tracheal pressure and flow, demands are placed on the valve that are not fully met by prior valves which either are unable to or require manual adjustment to  
15 meet the demands. Further, prior valves have internal rather than external tracheal attachments that are awkward to use and/or require neck band supports, are frequently bulky and unattractive, and are relatively complex in construction.

20 It is therefore desirable to provide a tracheal valve that will automatically remain open during normal breathing, will close during voice exhalation, and will open during coughing, and is simple in construction, relatively small in  
25 size, reliable in operation, convenient and durable

in use and affixed over rather than in the tracheal airway.

According to the present invention there is provided apparatus for use in a tracheotomy stoma  
5 comprising a valve for controlling fluid communication through the stoma responsive to the tracheal fluid pressure and flow and means for removably attaching said valve for fluid communication with the stoma, in which the valve comprises a valve seat and a valve element,  
10 the valve element being movable between first, second and third positions, the first position being used for normal breathing to provide fluid flow through said valve, the valve element being moved to the second position by voice exhalation to engage the valve seat  
15 thereby to occlude fluid flow through said valve, and the valve element being moved to the third position by high tracheal cough pressures to provide a fluid flow through said valve.

Such a tracheal valve will automatically adjust to  
20 the various breathing, voice, and coughing conditions. It can be made so that it is versatile in operation, reliable, convenient and durable in use, simple in construction and so relatively small in size and can be hidden by clothing in use.

25 The apparatus of this invention can readily be made to have a convenient and reliable attachment over rather than in the tracheo-stoma, and it is readily adaptable for use with a voice prosthesis and/or existing tracheotomy tubes.

30 The valve element preferably comprises a flexible resilient circular diaphragm that has a diametral fold and is centrally supported in a collar-shaped valve body. The fold opening is towards the trachea and is opened by exhalation from the trachea. The diaphragm  
35 thickness is such that during normal breathing the

diaphragm remains in a folded configuration, but on voice exhalation it unfolds and occludes the valve opening to divert voice exhalation to the larynx or a voice prosthesis. During a high pressure cough, the  
5 diaphragm may evert and thus provides a valve opening.

The valve assembly may have an adhesive-coated resilient annular skirt that makes an acute angle with the valve axis and adheringly seats on an adhesive concave washer which is adhesively attached to the  
10 tissue around the stoma. The valve may be used with or without a voice prosthesis. The diaphragm may be interchangeable with a different thickness diaphragm to suit the user's pulmonary status.

The abovementioned and other features and objects  
15 of this invention and the manner of obtaining them will become more apparent and the invention itself will be best understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

20 Figure 1 is an exploded perspective view of the improved tracheal valve of this invention;

Figure 2 is a partial sectioned view of the improved tracheal valve of this invention, circumferentially affixed to the skin around the  
25 tracheo-stoma;

Figure 3 is an enlarged sectioned view of the improved tracheal valve of this invention with the diaphragm in a position for inhalation;

Figure 4 is a view similar to Figure 3 showing a  
30 diaphragm position for normal exhalation;

Figure 5 is a view similar to Figure 3 showing a diaphragm position for voice exhalation;

Figure 6 is a view similar to Figure 3 showing the diaphragm in an everted position for cough exhalation;

Figure 7 is a sectioned partial view of the improved tracheal valve of this invention used with a voice prosthesis;

Figure 8 is a sectioned partial view of a modified  
5 tracheal valve of this invention used with a tracheotomy tube; and

Figure 9 is an enlarged sectioned partial view of the tracheal valve and tube of Figure 8.

Referring to Figures 1-6, valve assembly 20  
10 comprises a collar-shaped body 22 having annular outwardly extending flange 24 at a first end, annular rib 28 on its outer wall at its second end, and cross bar 30 extending diametrically across its second end, each end of bar 30 being secured to body 22. Post 32 is  
15 secured at one end to the centre of bar 30 and extends axially of body 22 towards the first end. Post 32 is tapered towards its other end to which is secured a T-shaped or enlarged retainer 34 which forms opposed  
20 recesses or recess portions 36, 38 with the end of post 32.

A flexible, resilient, lightweight, circular diaphragm 40 is formed with a diametral fold and has

leaves 42, 44 which are folded along fold line 46 and are resiliently displaceable from and resiliently returnable to the fold position. Opening 48 is formed centrally of diaphragm 40 and is fittable over and  
5 around retainer 34. The periphery of opening 48 snugly fits in recesses 36, 38 and thereby retains diaphragm 40 on the end of post 32.

A ring cap 50 has a central bore 52 and annular flange 54 at one end and annular boss 56 at the  
10 opposite end. Arcuate handle 58 is secured at its ends to the outer surface of flange 54. Cap 50 is removably retained in body 22 by forceful insertion until boss 56 finds groove 26, at which point flange 54 seats snugly on flange 24 and boss 56 is positioned in groove 26. A  
15 shoulder or valve seat 57 is defined by the end of cap 50 adjacent boss 56 when inserted into body 22. Handle 58 provides a grip for removal out of sleeve 60 and also acts as a clothing guard to keep user garments and the like from interfering with valve operation or entering  
20 the stoma during use.

A flexible, resilient, cylindrical sleeve 60 has an annular recess 61 on its inside wall at one end thereof. Annular, flexible, resilient skirt 62 is secured to the outside wall of sleeve 60 opposite recess  
25 61. The surface of skirt 62 is angled toward the wall of sleeve 60 to provide the second end of assembly 20 with a convex configuration conforming to the tissue around the stoma. A dual-sided annular tape 66 is substantially coextensive with and conforming to skirt  
30 62 and has adhesive applied to both surfaces 68, 70 thereof. Surface 64 is adhesively applied to surface 68 and surface 70 is adhesively placed on the tissue surrounding the stoma which has been surgically conformed with a concave opening and prepared to receive  
35 tape 66. Body 22 is inserted into sleeve 60 until rib

- 6 -

28 fits into recess 61 at which time the rim of sleeve 60 seats against the underside of flange 24 and skirt 62 is removably secured to body 22.

Referring to Figs. 2 and 7, valve assembly 20 is shown attached to tissue 72 surrounding a tracheo-stoma 74 which provides an opening to trachea 76. In Fig. 7, a voice prosthesis 80 is shown inserted into stoma 74 through trachea 76 into esophagus 78. When the larynx has been surgically removed, a voice prosthesis may be required to bypass pulmonary air through esophageal or pharyngeal tissues to produce a laryngeal psuedo voice. However, the tracheal valve of the invention can be used as shown in Fig. 8 whenever the larynx remains intact. The prosthesis 80 shown has an elongated hollow tube 82 which may be of silicone material and has a length of 2.2 cm to 4.3 cm and an outside diameter of 5.4 mm. A razor thin longitudinal slit 84 is formed in the wall of tube 82 portion that is in esophagus 78. A port 86, in this embodiment 3.5 mm x 7.0 mm, is formed on the lower side of tube 82 portion in trachea 76. Elongated straps 88, 90 are secured to and extend radially from opposite sides of tube 82 wall at the outer end thereof. Straps 88, 90 lie against the user neck exterior to provide prosthesis retention. Tape 66 is placed over straps 88, 90, valve assembly 20 is placed against tape 66 and skin surrounding the stoma, and surface 64 adheres to surface 68.

Referring now to Figs. 3-6, the inhalation position of diaphragm 40 is shown in Fig. 3 with leaves 42, 44 lying adjacent the tapered sides of post 32. During normal breathing, leaves 42, 44 may be partially lifted by exhalation, Fig. 4, but do not occlude the valve passageway. During a voice exhalation, Fig. 5, leaves 42, 44 are fully extended and the outer



perimetral border of diaphragm 40 seats against shoulder 57 to effectively occlude air passage through assembly 20 and divert air into the larynx or, in the case of Fig. 7, into prosthesis 80. Voice exhalation would then be directed into port 86 of tube 82 to exit slit 84 into the esophagus and produce a voice sound. Slit 84 acts as a one-way valve preventing entrance of matter from esophagus 78 but permitting passage of air through slit 84. High pressure coughing exhalation may cause diaphragm 40 to evert, Fig. 6, forcing the perimetral edges of diaphragm 40 past shoulder 57 and through opening 32 providing for escape of cough flow.

Thus, the valve assembly 20 automatically accommodates the breath flow and pressures associated with normal breathing, speaking, and coughing. If diaphragm 40 everts during high pressure coughing, it is manually reset by moving leaves 42, 44 back through opening 52. Diaphragm 40 is interchangeable with diaphragms of different thicknesses to accommodate the pulmonary status of the user. For example, for those who are light breathers, such as older persons or those who suffer from emphysema, a thinner diaphragm is used. For normal breathing persons, a medium thickness is used. For heavy breathers, a thicker diaphragm is selected.

The diaphragm material may be of an opaque latex material such as sold by American Latex, Sullivan, Indiana. Body 20, sleeve 60, and skirt 62 may be of a medium grade polyvinyl chloride (PVC) plastic material. The adhesive used on double-sided adhesive tape 66 and skirt 62 may be a hypoallergenic adhesive tape such as 3M 1509. The surfaces surrounding the stoma may be prepared by coating with Ace adherent liquid adhesive additive available from Becton Dickinson Consumer Products.

Referring to Figs. 8 and 9, a modified valve of this invention is shown that is usable with a conventional tracheotomy tube 92 which is inserted into the trachea below the larynx. Tube 92 will not be described except to note that it has tubular end 94 onto which the valve of this invention can be removably secured. Cap 100 has external threads 102 but otherwise is essentially the same as cap 50. Body 104 has internal threads 106 to provide for removable retention of cap 100 in body 104, but is otherwise essentially the same as body 22. Body 104 is provided with a tubular extension 110 which receives in a fluid-tight friction fit end 94 therein. Cap 100 and body 104 correspond to cap 50 and body 22, respectively, in the valve of Figs. 1-7, with the diaphragm 40 being supported and operating in the manner previously described. As desired, cap 50 and body 22 may be provided with the threads 102, 106 or, alternatively, cap 100 and body 104 may be provided with boss 56 and groove 26 to accomplish the removable retention of the caps on the bodies. Similarly, the body 22 may be provided with an extension 110, thereby providing an adaptive connection to conventional tracheotomy tubes as desired.

While there have been described above the principles of this invention in connection with specific embodiments, it is to be understood that this is by way of example and is not limiting of the scope of this invention.

C L A I M S

1. Apparatus for use in a tracheotomy stoma comprising a valve (20) for controlling fluid communication through the stoma (74) responsive to the tracheal fluid pressure and flow and means (60-70) for  
5 removably attaching said valve for fluid communication with the stoma, characterised in that said valve (20) comprises a valve seat (57) and a valve element (40), the valve element being movable between first, second and third positions, the first position being used for  
10 normal breathing to provide fluid flow through said valve, the valve element being moved to the second position by voice exhalation to engage the valve seat thereby to occlude fluid flow through said valve, and the valve element being moved to the third position by  
15 high tracheal cough pressures to provide a fluid flow through said valve.

2. Apparatus according to claim 1, characterised in that the valve comprises a collar-shaped cylindrical body (22), on which is formed said valve seat (57) and  
20 in that said valve element comprises a flexible, diaphragm (40) and in that means (32 to 38) are provided for supporting the diaphragm at its centre within said body.

3. Apparatus according to claim 3, characterised in  
25 that said diaphragm (40) comprises two leaves (42, 44) folded towards one another about a fold line, said leaves being resiliently displaceable from and returnable to the fold position, said first position of the valve element comprising said leaves being in the  
30 folded position, the second position comprising said

leaves being in an unfolded position and said third position comprising said leaves being folded in an everted position.

4. Apparatus according to claim 3, characterised in  
5 that said support means (32 to 38) is capable of supporting the diaphragm in said body in such a manner whereby said diaphragm is changeable with other diaphragms of different physical properties to accommodate different breathing conditions.

10 5. Apparatus according to claim 4, characterised in that diaphragms (40) of different thicknesses are used for conditions of varying pulmonary status.

6. Apparatus according to any of claims 2 to 5,  
characterised in that the collar-shaped body (22) has a  
15 first end (24) and a second end attached to said stoma, in that a ring cap (50) is held in the first end and a rim of the ring cap forms a shoulder which provides the valve seat (57).

7. Apparatus according to claim 6, characterised in  
20 that said ring cap has an arcuate handle (58) secured at each end to opposite diametral points on the cap.

8. Apparatus according to claim 5, 6 or 7,  
characterised in that the means for attaching the valve for fluid communication with the stoma comprises a  
25 resilient, flexible, annular skirt (62) fitted on the second end of the body, said skirt being flared towards said body so that it is convexly configured to conform to the stoma opening.

9. Apparatus according to claim 8, characterised in that an adhesive is applied to the convex surface of said skirt, said skirt being adapted for attaching to the tissue around the stoma, whereby when the diaphragm  
5 is in its second position, tracheal air flow will be directed into the esophagus or pharinx to produce a psuedo-voice.

10. Apparatus according to any of claims 2 to 9, characterised in that it includes a tubular extension  
10 (110) adapted to be inserted over a tracheotomy tube end (94) and secured thereto.

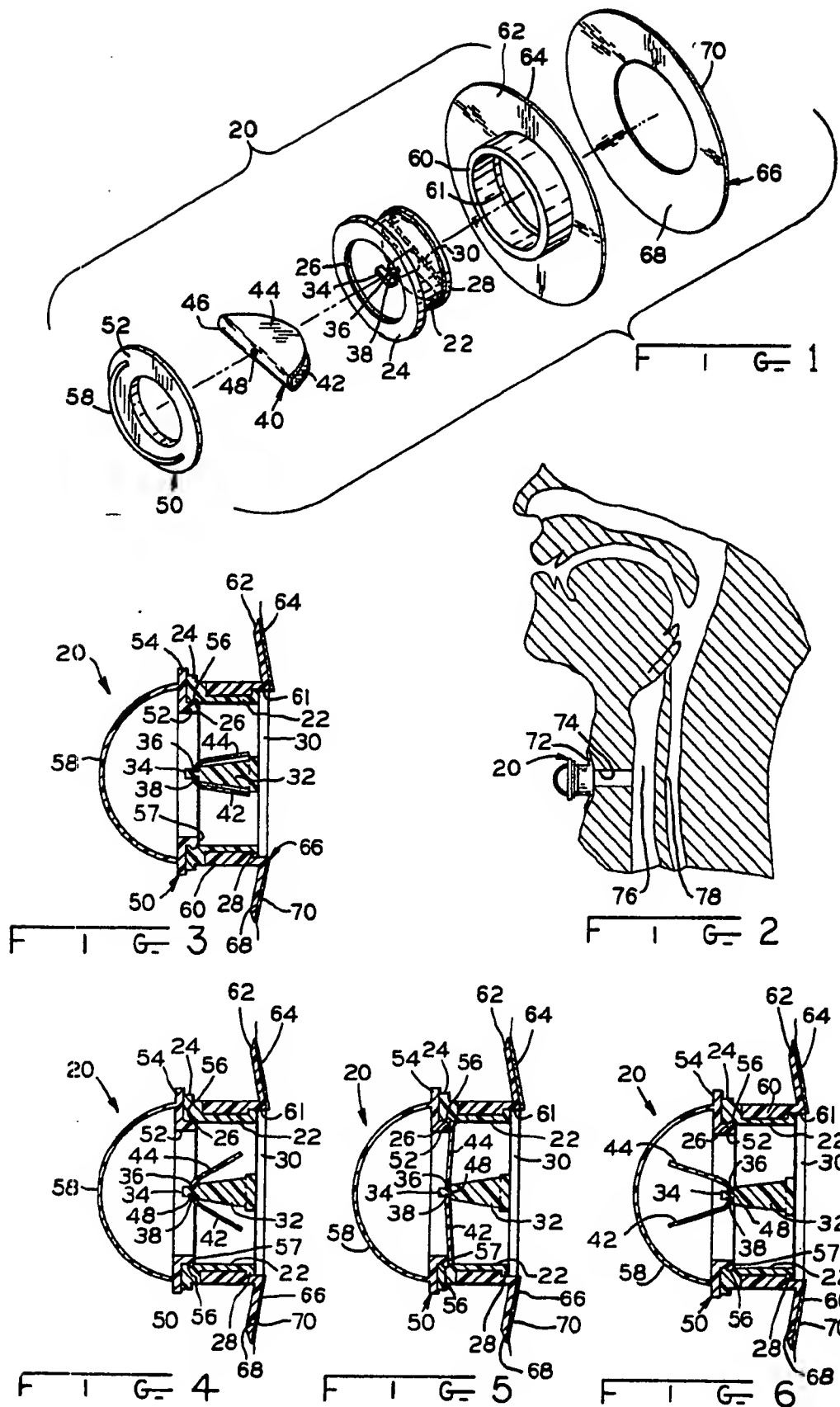
11. Apparatus according to any one of claims 2 to 10, characterised in that it includes a voice prosthesis (80) adapted for insertion into the tracheal stoma, said  
15 body second end being placed over said voice prosthesis and adapted for attachment to the tissue around the stoma, whereby when the valve element is in its second position, airflow will be directed through said voice prosthesis to produce voice sounds.

20 12. Apparatus according to claim 11, characterised in that said voice prosthesis comprises an elongate tube (82) adapted to be inserted through the trachea and into the esophagus, a longitudinal razor slit (84) being formed in the tube portion in the esophagus to provide a  
25 one-way valve and in that a port (86) is formed in the tube in the trachea portion of the tube to receive tracheal air, said tube conducting said air to said slit when the valve element is in its second occluding position.

30 13. Apparatus for use in a tracheotomy stoma

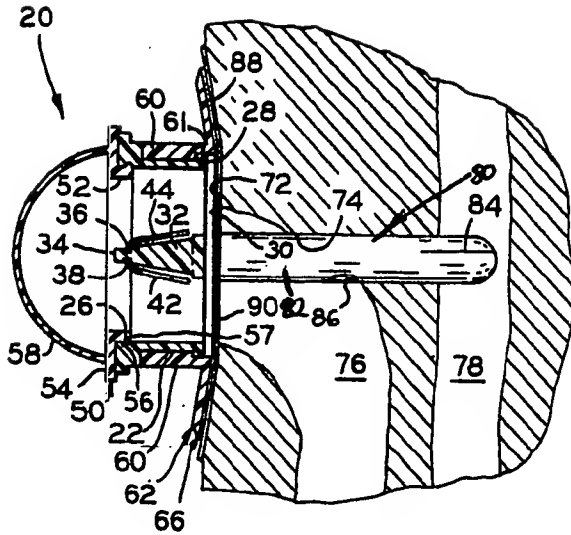
comprising a valve (20) for controlling fluid communication through said stoma, responsive to tracheal fluid pressure flow and means for removably attaching said valve for fluid communication with said stoma,  
5 characterised in that said attaching means is attachable only to the exterior tissue surrounding the stoma whereby the valve may be affixed over, rather than in, the tracheal airway.

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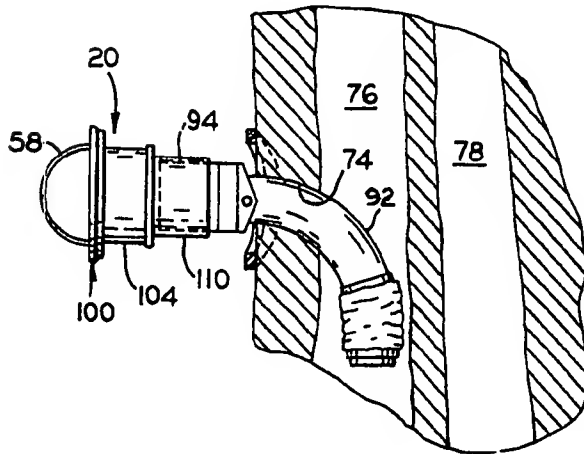


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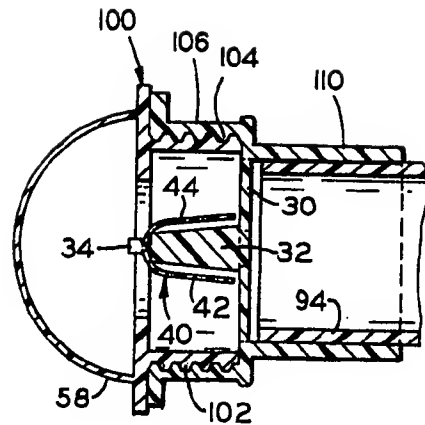
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F I G. 7



F I G. 8



F I G. 9





European Patent  
Office

# EUROPEAN SEARCH REPORT

0078685

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 82305776.5
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 8)
X	US - A - 3 952 335 (P.S. SORE, E.W. CLIFFORD)	1	A 61 M 16/00 A 61 F 1/20
Y	* Totality, especially column 9, line 44 - column 10, line 53 *	2,6,10	
A	--	11-13	
Y	US - A - 3 137 299 (C.J. TABOR)	2,6,10	
A	* Totality *	1,13	
P,A	US - A - 4 325 366 (C.J. TABOR) * Fig. 1,2; column 2, line 24 - column 3, line 25 *	1,2,6, 8,13	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 8)
			A 61 M 16/00 A 61 F 1/00 A 61 B 17/00
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 07-02-1983	Examiner LUDWIG
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	